INTERVIEW SUMMARY

A telephonic interview was conducted on July 12, 2005. Applicants thank Supervisory Patent Examiner Tsang for the courtesies extended to their representative, Kevin L. McLaren. In a prior action, the captioned application was subject to a restriction requirement imposed by Examiner Morris. Applicants had previously requested reconsideration of the initial grouping under 35 U.S.C. § 121, which grouping placed the compound claims 1-2 with the pharmaceutical composition claims 3-4. Applicants suggested that pharmaceutical composition claims 3-4 were more properly grouped with the method of treating claims 5-14. That request was denied by Examiner Morris. Regardless, during the telephonic interview of July 12, 2005, Supervisory Patent Examiner Tsang agreed that the restriction requirement imposed by Examiner Morris was improper. Examiner Tsang verbally withdrew that requirement and suggested that the method of treating claims be reintroduced and the pharmaceutical composition claims canceled by Applicants. Further, Supervisory Patent Examiner Tsang indicated that such method of treating claims would be allowed following Applicants' response demonstrating proper support therefor in the specification. Accordingly, Applicants submitted by facsimile transmission on July 15, 2005, an amendment including new claims 18-27, corresponding to the originally filed method of treating claims, and canceling the pharmaceutical composition claims 3-4. The captioned application was subsequently assigned to Examiner Chang.

A second telephonic interview was conducted on August 15, 2005. Applicants also thank Examiner Chang for the courtesies extended to their representative, Kevin L. McLaren. Examiner Chang indicated that, under Patent Office rules, Applicants' faxed Amendment of July 15, 2005, would not be entered because Applicants' election in response to the restriction requirement imposed by Examiner Morris was made without traverse. Examiner Chang also indicated that the captioned application could be examined under an RCE, whereupon rejoined compound claims, pharmaceutical composition claims, and method of treating claims would likely be restricted under a new restriction requirement on the basis of compound structure. Accordingly, Applicants' amendment submitted herewith under an RCE includes amended pharmaceutical composition claims 3-4, and new method of treating claims 18-27 corresponding to originally filed method of treating claims 5-14, which were previously canceled.

REMARKS

In the captioned application, claims 3-4 stand finally rejected under 37 C.F.R. § 1.113 as being anticipated or rendered obvious under 35 U.S.C. §§ 102(a), (b), and/or (e) and § 103(a). Examiner Morris has cited the following references in support thereof: Czekaj et al. in US 2003/0092698; Tulshian et al. in US 6,727,254; Pauls et al. in US 2002/0045613; Altenburger et al. in US 6,680,329; Ewing et al. in WO 01/07436; Bastian et al. in US 6,265,416; Chen et al. in US 5,990,109; Doll et al. in US 5,880,128; Tanga et al. in CA 127: 161747; Takefuji et al. in US 5,763,463; Konishi et al. in JP 3-181462; Shimizu et al. in CA 112:193716; Matondo et al. in J. Agric. Food Chem. 1990, 38, 1106-1109; Kirazis et al. in CA 112:138873; Sakamoto et al. in CA 108:75166; Von Bebenburg et al. in CA 93:95098; Bickel et al. in US 3,929,779; Pews et al. in US 3,804,844; Yakhontov et al. in CA 69:86786; Imperial Chemical in CA 68:59438; Clark-Lewis et al. in CA 57:23142; and Takahashi et al. in CA 51:12837.

Claims 3 and 4 also stand finally rejected under 35 U.S.C. § 112, second paragraph, as being indefinite "for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Examiner Morris contends that claim 3 "provides for the use of treating injured mammalian nerve tissue but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass." Examiner Morris also contends that the recitation of "salts" in claim 4 "makes claim 4 read on mixtures rather than specific compounds."

Finally, claim 3 also stands finally rejected under 35 U.S.C. § 101 as an allegedly improper process claim because Examiner Morris indicates that claim 3 recites "...a use, without setting forth any steps involved in the process,...".

Pursuant to the telephonic interview conducted on August 15, 2005, Applicants amendment submitted herewith is filed under an RCE. Applicants have amended pharmaceutical composition claims 3-4, such that claim 3 more clearly presents claim elements and such that the claims again recite solvates of the recited compound. Amended pharmaceutical composition claims 3-4 contain no new matter. Applicants respectfully submit that a person of ordinary skill in the art would recognize that the formation of solvates is a likely, if not an expected, result when compounds are prepared or recrystallized, in general, and in particular when solvents or solvent combinations such as methanol, ethyl acetate, water and/or methanol-water are employed in such preparations or in such recrystallizations, as in the captioned application (*see generally*, pp. 16-19; Syntheses).

Further under an RCE, Applicants have added new method of treating claims 18-27, which, other than depending from amended pharmaceutical composition claim 3, are essentially identical to originally filed method of treating claims 5-14, which were previously canceled, and therefore contain no new matter. Applicants specifically point to the support for new method of treating claims 18-27, which is provided in the specification on page 4, under OBJECTS OF THE INVENTION; page 5, under SUMMARY OF THE INVENTION; page 7, in the last paragraph thereon; and throughout the Examples presented on pages 24-38, of the application as filed. The invention defined by new claims 18-27 is drawn to novel methods for treating mammals "suffering from injured mammalian nerve tissue." The methods include the step of administering a particularly substituted 4-aminopyridine compound or analog or derivative thereof in a pharmaceutical composition. Applicants have discovered that such compounds when administered *in vivo* reduce "the deleterious effect of PNS or CNS tissue injury, ... by restoring action potential or nerve impulse conduction through the nerve tissue lesion" (p. 8, paragraph 2). *In vitro* tests of the claimed compounds using "double sucrose gap *in vitro* recording" demonstrated their ability for general excitation of neural circuits (*see generally*, pp. 24-27; FIGS. 1 & 6). Moreover, *in vivo* testing of the compounds established their effectiveness for restoring nerve impulse conduction through damaged regions of the spinal cord white matter, as measured by "somatosensory evoked potential testing" (SSEP) (*see generally*, pp. 27-31; FIGS. 2 & 7). Preparation of the animal models used for that *in vivo* testing is described on page 31, paragraphs 2-3; the SSEP testing is described on pages 31-32; drug administration is described on pages 32-33; and dosages are described on page 33, paragraph 2. Finally, the results of these *in vivo* and *in vitro* tests are generally described on pages 33-38, and in Table 1 on page 37.

As stated above, the captioned application stands finally rejected under Sections 101, 102, 103, and 112 of the Patent Laws. Applicants again traverse Examiner Morris's rejection under 35 U.S.C. §§ 102(a), (b), and/or (e), and consider that none of the references cited by Examiner Morris anticipate claims 3 and 4. Applicants also again traverse Examiner Morris's rejection under 35 U.S.C. § 103(a) and consider claims 3 and 4 to be patentable over the combination of those references cited by Examiner Morris under 35 U.S.C. §§ 102(a), (b), and/or (e). In addition, Applicants again traverse Examiner Morris's rejection of claims 3 and 4 under 35 U.S.C. § 112, second paragraph, as well as Examiner Morris's rejection of claim 3 under 35 U.S.C. § 101. Therefore, Applicants request reconsideration of Examiner Morris's rejections of claims 3 and 4 under 35 U.S.C. §§ 102(a),

(b), and/or (e); 35 U.S.C. § 103(a); 35 U.S.C. § 112, second paragraph; and 35 U.S.C. § 101 pursuant to the arguments presented below.

In the rejection of Applicants' claims 3 and 4 under 35 U.S.C. §§ 102(a), (b), and/or (e), Examiner Morris contends that the instant claims are anticipated by Czekaj et al., Tulshian et al., Pauls et al., Altenburger et al., Ewing et al., Bastian et al., Chen et al., Doll et al., Tanga et al., Takefuji et al., Konishi et al., Shimizu et al., Matondo et al., Kirazis et al., Sakamoto et al., Von Bebenburg et al., Bickel et al., Pews et al., Yakhontov et al., Imperial Chemical, Clark-Lewis et al. and Takahashi et al. "for the reasons set forth in the previous Office action." Examiner Morris specifically states that "[c]ontrary to applicants' arguments in the instant response, the references teach pharmaceutical compositions containing the instant compounds" and that "[a] pharmaceutical composition is nothing more than the compound plus an inert carrier."

Applicants respectfully submit that in order "[f]or a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference." In re Bond, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). Accordingly, Applicants note that claims 3 and 4 are directed to a "pharmaceutical composition" that includes the recited compound "in an amount effective for the treatment of injured mammalian nerve tissue." In contrast, the afore-mentioned references cited by Examiner Morris fail to teach a pharmaceutical composition, either implicitly, inherently, or explicitly for the treatment of injured mammalian nerve tissue. Further, Examiner Morris's assertion that "[a] pharmaceutical composition is nothing more than the compound plus an inert carrier" is overly simplistic. Benzene is an inert carrier because when used as a solvent it is generally non-reactive, but it can hardly be considered a pharmaceutically acceptable carrier. Similarly, though the compositions that are disclosed by the cited references recite carriers, those carriers are not pharmaceutically acceptable. In particular, those references recite organic solvents such as dimethylformamide, tetrahydrofuran, ethyl acetate, acetonitrile, and the like.

Moreover, while the afore-mentioned references cited by Examiner Morris may disclose compounds that fall within the scope of the structure represented by the formula recited in Applicants' claims 3 and 4, there is no mention of those compounds combined in the form of a pharmaceutical composition, including a "pharmaceutical composition comprising a compound in an amount effective for the treatment of injured mammalian nerve tissue," as required by Applicants' claims 3 and 4. Shimizu et al., Von Bebenburg et al., Takefuji et al., and Imperial Chemical disclose compounds potentially useful as

anticytokinins, antiphlogistics, analgesics, herbicides, insecticides, pesticides, fungicides, and nematocides. Kirazis et al., Sakamoto et al., Yakhontov et al., Takahashi et al., Clark-Lewis et al., Pews et al., Matondo et al., and Tanga et al. disclose compounds used in chemical reaction studies, compounds produced by a chemical process to illustrate potential utility thereof, and compounds that confirm the outcome of a particular chemical synthesis. Ewing et al., Czekaj et al., Tulshian et al., Pauls et al., Altenburger et al., Bastian et al., Chen et al., Doll et al., and Bickel et al. disclose pharmaceutical compositions, but none of those pharmaceutical compositions include compounds that fall within the scope of the structure represented by the formula recited in Applicants' claims 3 and 4. Further, the pharmaceutical compositions that are disclosed in Ewing et al., Czekaj et al., Tulshian et al., Pauls et al., Altenburger et al., Bastian et al., Chen et al., Doll et al., and Bickel et al. are described as being intended for coagulative disorders, protein tyrosine kinase-associated disorders, antibacterial use, treatment of human cancer, and treatment of cough, pain, anxiety, asthma, alcohol abuse or depression.

Simply, each of Czekaj et al., Tulshian et al., Pauls et al., Altenburger et al., Ewing et al., Bastian et al., Chen et al., Doll et al., Tanga et al., Takefuji et al., Konishi et al., Shimizu et al., Matondo et al., Kirazis et al., Sakamoto et al., Von Bebenburg et al., Bickel et al., Pews et al., Yakhontov et al., Imperial Chemical, Clark-Lewis et al. and Takahashi et al. is silent to the inclusion of the compounds recited in Applicants' claims 3 and 4 in the claimed pharmaceutical composition for the treatment of injured mammalian nerve tissue, let alone in amounts effective for the same. Therefore, Applicants respectfully submit that the afore-mentioned references cited by Examiner Morris, and the compounds disclosed therein, fail to teach each limitation of claims 3 and 4. As such, these references are incapable of anticipating Applicants' claims 3 and 4.

In the rejection of Applicants' claims 3 and 4 under 35 U.S.C. § 103(a), Examiner Morris contends that the instant claims are unpatentable over the combined teachings of Czekaj et al., Tulshian et al., Pauls et al., Altenburger et al., Ewing et al., Bastian et al., Chen et al., Doll et al., Tanga et al., Takefuji et al., Konishi et al., Shimizu et al., Matondo et al., Kirazis et al., Sakamoto et al., Von Bebenburg et al.,Bickel et al., Pews et al., Yakhontov et al., Imperial Chemical, Clark-Lewis et al. and Takahashi et al. "for the reasons set forth in the previous Office action." Examiner Morris specifically states that "the references generically embrace the instant composition containing the compounds," "[a]pplicants appear to couch their arguments in terms of use," and that "applicants are merely claiming pharmaceutical compositions that contain the instant compounds."

As stated above in response to Examiner Morris's rejections under 35 U.S.C. §§ 102(a), (b), and/or (e), Applicants' claims 3 and 4 are directed to a "pharmaceutical composition comprising a compound in an amount effective for the treatment of injured mammalian nerve tissue." Thus, Applicants are indeed "claiming pharmaceutical compositions that contain the instant compounds." However, those claimed pharmaceutical compositions require "a compound in an amount effective for the treatment of injured mammalian nerve tissue." As stated above in Applicants' response to Examiner Morris's rejections under 35 U.S.C. §§ 102(a), (b), and/or (e), none of the afore-mentioned references cited by Examiner Morris teach a pharmaceutical composition, either implicitly, inherently, or explicitly for the treatment of injured mammalian nerve tissue. Further, because those references are silent to the inclusion of the compounds recited in Applicants' claims 3 and 4 in the claimed pharmaceutical composition "in an amount effective for the treatment of injured mammalian nerve tissue," even if every reference is taken together, the resulting massive combination fails to arrive at Applicants' invention. There is simply no suggestion, teaching, or motivation that the compounds disclosed in the cited references could be included in a pharmaceutical composition "for the treatment of injured mammalian nerve tissue." Therefore, and contrary to Examiner Morris's contention, even if the person of ordinary skill in the art would have been motivated to combine the cited references, such a combination fails to arrive at Applicants' invention as defined by claims 3 and 4. As such, these references are incapable of rendering obvious Applicants' claims 3 and 4.

In the rejection of Applicants' claim 3 under 35 U.S.C. § 112, second paragraph, and under 35 U.S.C. § 101, Examiner Morris contends that the instant claim "provides for the use of treating injured mammalian nerve tissue but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass" and "results in a claim which is not a proper process claim under 35 U.S.C. 101," respectively. However, Examiner Morris also specifically states that "applicants are claiming compositions" and that "the recitation of use needs to be deleted." Applicants respectfully refer to the preamble of amended claim 3, which sets forth the statutory class of the invention, and reads: "A pharmaceutical composition..." (emphasis added). Accordingly, Applicants respectfully point out that claim 3 is a composition claim, and not a method nor a process claim, and is therefore not required to set forth any steps related thereto. Nevertheless, Applicants have amended claim 3 to clarify that the effective amount of the compound present in the claimed pharmaceutical composition is that which is

effective in treating injured mammalian nerve tissue. Accordingly, Applicants believe that claims 3-4 comply with the requirements of Sections 101 and 112 of the Patent Laws.

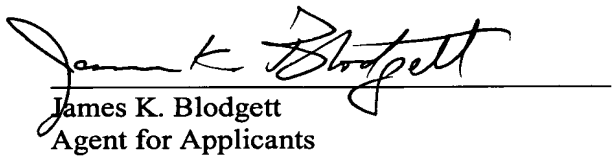
In the rejection of Applicants' claim 4 under 35 U.S.C. § 112, second paragraph, Examiner Morris contends that the recitation of "salts" therein allegedly "makes claim 4 read on mixtures rather than specific compounds." Applicants respectfully point out that claim 4 depends from claim 3, which recites a pharmaceutical composition that includes an effective amount of the recited formula, as defined in claim 3, or a pharmaceutically acceptable salt or solvate of that formula. Claim 4, depending from claim 3, recites a Markush group that includes specific examples of those compounds falling within the scope of the formula recited in claim 3. Therefore, and implicitly, pharmaceutically acceptable salts or solvates of those specific examples recited in claim 4 are also intended to be included in the scope of the compounds recited in claim 4. Because the proper Markush recitation requires the conjunction "and," there is an implicit plurality to the grammar. In other words, the Markush listing does not refer to a single salt, but rather a variety of pharmaceutically acceptable salts that may be made from the listed compounds. Therefore, Applicants believe that the plural "salts" in claim 4 properly refers to the preceding list of compounds, and therefore a plural is grammatically necessary.

Further, Examiner Morris's rejection appears to center on her interpretation that the plural "salts" makes "claim 4 read on mixtures." Applicants respectfully point out that claim 3, and therefore claim 4 which depends from claim 3, are open-ended claims, and refer to Applicants' use of comprising language in claim 3, with reference to the claimed pharmaceutical composition. Thus, claim 3 recites the requirements defining its scope. However, it is to be understood that since that claim is open-ended, any composition, including any mixture, that otherwise meets the specific limitations recited in claim 3 falls within the scope of claim 3. Correspondingly, claim 4, which only further refines the definition of the compound recited in the claimed pharmaceutical composition, also includes any mixture which otherwise meets the limitations recited in claim 4. Hence, Applicants believe that the use of the plural "salts" is proper and definite. Nevertheless, Applicants have amended claim 4 by moving the modifying phrase prior to the Markush group to simplify the grammar. Accordingly, Applicants respectfully request withdrawal of the rejection of claim 4 on that basis.

CONCLUSION

Based on the foregoing amendments to the claims and the accompanying remarks, Applicants believe that all outstanding rejections of claims 3-4 have been resolved. Applicants further submit that new claims 18-27 are fully supported by the instant specification as filed, and consider the instant claims to be in condition for allowance. Accordingly, Applicants respectfully request reconsideration of the standing rejections, leading to their withdrawal, and passage of the instant application to issuance.

Respectfully submitted,
BARNES & THORNBURG LLP



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